

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

NOVARTIS AG, NOVARTIS
PHARMACEUTICALS CORPORATION,

Plaintiffs,

v.

NOVADOZ PHARMACEUTICALS LLC,
MSN PHARMACEUTICALS INC., MSN
LABORATORIES PRIVATE LIMITED,

Defendants.

No. 25-CV-00849-EP-JRA

**DEFENDANTS' MEMORANDUM OF LAW IN RESPONSE TO THE
COURT'S ORDER FOR BRIEFING ON RECONSIDERATION**

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MSN¹ respectfully submits this brief in response to the Court’s April 4, 2025 order informing the parties that it was considering *sua sponte* reconsidering its order granting Novartis’s motion for a preliminary injunction (ECF 32, hereinafter the “Order”) and directing the parties to “brief this issue under the reconsideration standard as well as address what impact a potential reconsideration would have on the pending motion to stay.” ECF 43.

PRELIMINARY STATEMENT

The Court should reconsider and vacate its Order. As shown in parallel briefing on MSN’s Motion to Stay, MSN is likely to show that the Court erred in its analysis of irreparable harm, misapplied substantive trademark law, and did not make a required determination that Novartis was likely to prevail on all four preliminary injunction factors. The Court correctly acknowledged the Order would cause “substantial harm” to MSN and acknowledged the vital public interest in access to affordable prescription medication. The Court should correct these legal errors and prevent manifest injustice by vacating the Order under its broad inherent discretion or the standard for reconsideration.

Prior to the Court’s April 4, 2025 order, MSN filed its notice of appeal of the Court’s preliminary injunction order. ECF 35. Federal Rule of Civil Procedure 62.1

¹ MSN adopts the same defined terms as set forth in its motion for a stay of the preliminary injunction order, unless otherwise specified. ECF 37-1 (“Stay Mot.”).

prescribes the procedural path for the Court to reconsider its Order under such circumstances:² the Court should issue an indicative ruling that it intends to grant reconsideration and dissolve the preliminary injunction if the appeal is remanded.

See Fed. R. Civ. P. 62.1. MSN will then immediately petition the Third Circuit for a remand, and following remand this Court can issue a final, appealable ruling on reconsideration. MSN would then dismiss its appeal.

With respect to the pending Stay Motion, the Court retains jurisdiction to stay the injunction despite the notice of appeal. *See Fed. R. Civ. P. 62(d)* (granting district courts power to “suspend” or “modify” an injunction “[w]hile an appeal is pending”). Thus, if the Court is inclined to grant reconsideration, it should in the interim grant the Stay Motion and suspend the Order pending completion of the procedural steps set forth above. Even if the Court is not inclined to grant reconsideration, it should still grant the Stay Motion pending appeal, for the reasons set forth in MSN’s briefs in support of the Stay Motion.

ARGUMENT

I. Legal Standard.

² Although the Court retains jurisdiction to *stay* its preliminary injunction pending appeal, *see Fed. R. Civ. P. 62(d)*, the Court was otherwise divested of traditional jurisdiction to *reconsider and dissolve* that preliminary injunction when MSN filed its notice of appeal. *See Ortho Pharm. Corp. v. Amgen, Inc.*, 887 F.2d 460, 464 (3d Cir. 1989); *Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982) (“The filing of a notice of appeal . . . divests the district court of its control over those aspects of the case involved in the appeal.”).

The Court has “inherent power” over its own interlocutory orders and can reconsider them *sua sponte* “when it is consonant with justice to do so.” *United States v. Jerry*, 487 F.2d 600, 605 (3d Cir. 1973); *accord Thomson Reuters Enter. Ctr. GMBH v. Ross Intel. Inc.*, --- F. 3d Supp. ---, 2025 WL 458520, at *1 (D. Del. Feb. 11, 2025) (Bibas, J.) (*sua sponte* reconsidering denial of summary judgment); *Marsden v. Select Med. Corp.*, 2007 WL 518556, at *1 (E.D. Pa. Feb. 12, 2007) (*sua sponte* reconsidering denial of motion to dismiss).

Just as the Court’s decision whether to issue a preliminary injunction lay within its sound discretion, so would a subsequent decision to vacate it. *See, e.g., USNile Ltd. Liab. Co. v. StormIPTV*, 2014 WL 4637218, at *3, *6 (D.N.J. Sept. 16, 2014) (vacating a previously issued injunction under court’s “inherent authority to modify a preliminary injunction”). Reconsideration of a preliminary injunction is especially appropriate here given the abbreviated factual record before the Court at this initial stage of the case and the expedited nature of the briefing. *See Pueblo of Pojoaque v. State of New Mexico*, 221 F. Supp. 3d 1289, 1297 (D.N.M. 2016) (“The decision [to reconsider a preliminary injunction] should account for the fact that a preliminary injunction is often granted under pressured time constraints, on limited evidence and expedited briefing schedules.”).

In the alternative, the Court can reconsider the Order under the standard for a motion for reconsideration, as MSN has shown in its briefing on the Stay Motion

that there is “the need to correct a clear error of law or fact or to prevent manifest injustice.” *Max’s Seafood Cafe ex rel. Lou-Ann, Inc. v. Quinteros*, 176 F.3d 669, 677 (3d Cir. 1999); *see, e.g.*, *United States v. Riverside Med. Grp., P.C.*, 2024 WL 5182395, at *1 (D.N.J. Dec. 20, 2024) (granting reconsideration to correct two clear errors of law); *Resorts Int’l, Inc. v. Greate Bay Hotel & Casino, Inc.*, 830 F. Supp. 826, 832 (D.N.J. 1992) (granting reconsideration of prior summary judgment order on trademark infringement claim).

II. The Court Should Exercise Its Discretion to Deny Novartis’s Requested Preliminary Injunction.

As MSN has extensively briefed in opposition to Novartis’s preliminary injunction motion and in support of its Stay Motion, there exist ample grounds to reconsider the Order. That order was based on the following errors of law:

- (1) The Court did not find that Novartis prevailed on all four preliminary injunction factors, in contravention of black letter Third Circuit precedent. *See* Stay Mot. at 33; Order at 18.
- (2) The Court erred in its application of the legal framework for analyzing irreparable harm in trademark cases and accepted Novartis’s entirely speculative theory of irreparable harm unsupported by any record evidence. *See* Stay Mot. at 8–15; Order at 17–18.
- (3) The Court mistakenly applied a heightened standard for functionality that contravened binding Third Circuit caselaw. *See* Stay Mot. at 17–

20; Order at 9 (finding non-functionality based on the existence of alternatives for MSN).

- (4) The Court erred in holding that Novartis met its formidable burden to show its unregistered trade dress had acquired secondary meaning. The Court did not consider the overwhelming evidence of third-party use of the claimed trade dress features; erroneously held that Entresto's marketing materials were probative of secondary meaning, relied on a single affidavit from Novartis's paid expert as direct evidence of secondary meaning; and erroneously relied on Entresto's sales volume as probative of secondary meaning without evidence that those sales were driven by the trade dress. *See* Stay Mot. at 22–28; Order at 10–12.
- (5) The Court erroneously dismissed actual evidence of substantial hardship to MSN, including the loss of its first-mover advantage, as self-imposed, when MSN simply complied with FDA guidelines and standard industry practice—as did several other manufacturers seeking FDA approval for a generic version of Entresto. *See* Stay Mot. at 29–30; Order at 18.

(6) The Court failed to make any explicit finding on the public interest prong, notwithstanding its recognition of the “societal benefits of affordable alternatives to brand-name drugs.” Order at 18.

Thus, dissolving the Order would correct “clear error[s] of law” and prevent “manifest injustice” to MSN, other generic drug manufacturers, and heart failure patients writ large. *Max’s Seafood*, 176 F.3d at 677. Rectifying clear errors of law is no doubt “consonant with justice.” *Marsden*, 2007 WL 518556, at *1. Judge Bibas, sitting by designation in the District of Delaware, recently did just this in reconsidering *sua sponte* his prior decision on summary judgment. *Thomson Reuters*, 2025 WL 458520, *1.

Reconsideration is particularly appropriate here because Novartis has not relied on the Court’s earlier ruling and thus would not be prejudiced by reconsideration. See *DeFranco v. Wolfe*, 387 F. App’x 147, 156–57 (3d Cir. 2010) (affirming district court’s *sua sponte* reversal of prior denial of summary judgment where there was no prejudice to nonmovant). The preliminary injunction forces MSN to face “significant hardship.” Order at 18. Novartis cannot claim prejudice, because the preliminary injunction imposes no obligations on Novartis, and any loss of sales experienced by Novartis is fully compensable through money damages.³

³ The Order does not require Novartis to post any bond as required by Federal Rule of Civil Procedure 65, and MSN reserves its right to seek a bond if the Order is not stayed or dissolved.

III. The Court Should Suspend the Preliminary Injunction and Issue an Indicative Ruling.

Although the Court retains jurisdiction to *stay or suspend* the preliminary injunction pending appeal, *see Fed. R. Civ. P. 62(d)*, the Court lacks jurisdiction to *reconsider and dissolve* the preliminary injunction because it is the subject of a pending appeal, *see Griggs v. Provident Consumer Disc. Co.*, 459 U.S. 56, 58 (1982). But notwithstanding MSN’s pending appeal, there is a clearly defined procedural and jurisdictional path for the Court to reconsider the Order.

First, the Court should suspend the Order by granting MSN’s Stay Motion.⁴ Under Federal Rule of Civil Procedure 62(d), the Court retains jurisdiction to suspend a preliminary injunction even when the injunction has been appealed. Fed. R. Civ. P. 62(d); *Ortho Pharm.*, 887 F.2d at 463. To prevent irreparable harm to MSN and the public while the Court reconsiders its Order, *see Order at 18; Stay Mot. at 32–33*, the Court should stay its Order and restore the status quo for all the reasons set forth in MSN’s briefs in support of its Stay Motion. *See Stay Mot. at 28–30; Stay Mot. Reply at 2.*

Second, if the Court determines that it will grant the reconsideration motion and dissolve the Order, the Court should issue an indicative ruling pursuant to

⁴ Even if the Court decides not to reconsider its Order, it should still grant the Stay Motion to give MSN the opportunity to seek meaningful appellate relief, as explained in MSN’s briefs in support of the Stay Motion. Stay Mot. at 34; Stay Reply Br. at 4 n.3.

Federal Rule of Civil Procedure 62.1. Although the pendency of MSN's interlocutory appeal of the Order temporarily divests the Court of jurisdiction to dissolve the injunction, the Court retains the power to issue an indicative ruling that it will grant reconsideration under Rule 62.1, which permits this Court to state "that it would grant the motion if the court of appeals remands for that purpose or that the motion raises a substantial issue." Fed. R. Civ. P. 62.1(a)(3).⁵

Courts routinely issue indicative rulings in circumstances like this one—when a party seeks relief from a preliminary injunction while it is on appeal. *See Ivan A. v. Anderson*, 2021 WL 858608, at *3 (D.N.J. Mar. 8, 2021) (issuing indicative ruling that court would vacate preliminary injunction upon remand); *Pueblo of Pojoaque*, 214 F. Supp. 3d at 1123 (issuing indicative ruling that court "would dissolve or vacate the preliminary injunction if the [d]efendants dismiss the appeal and/or the

⁵ The Court can issue an indicative ruling even though MSN has not filed a formal motion for reconsideration. *See Index Newspapers LLC v. City of Portland*, 2022 WL 72124, at *2 (D. Or. Jan. 7, 2022) (collecting cases). The Court can construe this filing—made in response to the Court's request for briefing on reconsideration—as a motion for reconsideration, and find the motion to be timely given that it was filed in response to the Court's express instructions. Alternatively, the Court can construe MSN's Stay Motion, which was filed only seven days after the Order, as including a timely motion for reconsideration. *See, e.g., Mathis v. Christian Heating & Air Conditioning, Inc.*, 91 F. Supp. 3d 651, 656 (E.D. Pa. 2015) (treating motion for clarification as motion for reconsideration); *VanLeeuwen v. Farm Credit Admin.*, 577 F. Supp. 264, 272 (D. Or. 1983) (treating motion to stay preliminary injunction as motion for reconsideration of order granting preliminary injunction). As this brief reflects, the arguments warranting reconsideration are largely the same as those warranting a stay.

Tenth Circuit remands the case for the [c]ourt’s consideration”); *Index Newspapers LLC v. City of Portland*, 2022 WL 72124, at *10 (D. Or. Jan. 7, 2022) (same); *Ortiz y Pino v. Oliver*, --- F. Supp. 3d ---, 2025 WL 671821, *4 (D.N.M. Mar. 3, 2025) (granting defendant’s motion to dissolve preliminary injunction on remand following indicative ruling).

Should the Court issue an indicative ruling that it would reconsider its Order, MSN will immediately seek a limited remand of its Third Circuit appeal. *See* Fed. R. Civ. P. 62.1(b). Following remand, the Court can then dissolve the preliminary injunction consistent with its indicative ruling. *See* Fed. R. Civ. P. 62.1(c). Novartis could seek any appropriate relief from the Third Circuit after this Court’s resolution of the issue.

CONCLUSION

For the reasons stated herein, the Court should reconsider and deny the preliminary injunction.

Dated: April 7, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of April, 2025, I caused a copy of the foregoing to be served upon all counsel of record via ECF notification.

/s/ Rebekah Conroy
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